TITLE 4. PROFESSIONS AND OCCUPATIONS

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CHAPTER 18. NATUROPATHIC PHYSICIANS BOARD OF MEDICAL EXAMINERS

ARTICLE 1. GENERAL PROVISIONS

R4-18-101. Definitions

In addition to the definitions in A.R.S. §§ 32-1501 through 32-1581, the following definitions apply to this Chapter unless otherwise specified:

1. "Administrative completeness review" means the Board's process for determining that an applicant has provided, or caused to be provided, all of the application packet information and documentation required by statute or rule for an application for a license or a certificate.
2. "Applicant" means a person requesting from the Board an initial, temporary, or renewal license or certificate.
3. "Approved Specialty College or Program" means any postdoctoral training program that awards a medical specialist certificate and is approved by one of the following:
   a. The Council on Naturopathic Medical Education,
   b. The American Association of Naturopathic Physicians, or
   c. The Arizona Naturopathic Medical Association.
4. "Chief medical officer" means a physician who is responsible for a clinical, preceptorship, internship, or postdoctoral training program's compliance with state and federal laws, rules, and regulations.
5. "Continuing medical education" means courses, seminars, lectures, programs, conferences, and workshops related to subjects listed in A.R.S. § 32-1525(B), that are offered or sanctioned by one of the organizations referenced in R4-18-205 (B).
6. “Device” means the same as in A.R.S. § 32-1581(H)(1).
7. "Endorsement" means the procedure for granting a license in this state to an applicant who is currently licensed to practice naturopathic medicine by another state, district, or territory of the United States or by a foreign country that requires

a written examination substantially equivalent to the written examination provided for in A.R.S. § 32-1525.

8. "Facility" means a health care institution as defined in A.R.S. § 36-401, office or clinic maintained by a health care institution or by an individual licensed under A.R.S. Title 32, Chapter 13, 14, 17, or 29, office or public health clinic maintained by a state or county, office or clinic operated by a qualifying community health center under A.R.S. § 36-2907.06, or an office or clinic operated by a corporation, association, partnership, or company authorized to do business in Arizona under A.R.S. Title 10.
9. "Informed consent" means a document, signed by a patient or the patient's legal guardian, which contains the information in R4-18-802(A)(1), (A)(2), and (A)(3).
10. "Institutional review board" means a group of persons that is approved according to guidelines of the United States Department of Health and Human Services, Office for Human Research Protection, which reviews investigational or experimental protocols and approves their use on animals or humans for the purposes of protecting the subjects of the investigational or experimental protocol from undue harm and assures that the research and its review is carried out according to guidelines of the United States Department of Health and Human Services, Office for Human Research Protection.
11. "Internship" means clinical and didactic training by a doctor of naturopathic medicine certified by the Board according to A.R.S. § 32-1561.
12. "License" means a document issued by the Board that authorizes the individual to whom it is issued to practice naturopathic medicine.
13. “Medical student” means naturopathic medical student defined in A.R.S. § 32-1501(24).
14. “Medication” means the same as drug defined in A.R.S. § 32-1501(15) or natural substance defined in A.R.S. § 32-1501(23).
15. "National board" means any of the following:
    a. The Federation of State Medical Licensing Boards,
    b. The National Board of Chiropractic Examiners,
    c. The National Board of Medical Examiners,

d. The National Board of Osteopathic Examiners, or

e. The North American Board of Naturopathic Examiners.

16. “Procedure” means an activity directed at or performed on an individual for improving health, treating disease or injury, or making a diagnosis.

17. “Protocol” means an explicit detailed plan of an experimental medical procedure or test that is approved by an institutional review board.

18. "Resident physician in training" means a person who holds a degree of doctor of naturopathic medicine and is certified by the Board to diagnose and treat patients under supervision in an internship, preceptorship, or a post doctoral training program.

19. "Substantive review" means the Board's process for determining whether an applicant for licensure, certification, or approval meets the requirements of A.R.S. Title 32, Chapter 14 and this Chapter.

ARTICLE 8. EXPERIMENTAL MEDICINE

R4-18-801. Experimental Medicine

A procedure, medication, or device is experimental if:

1. An Institutional Review Board exists for a particular procedure, medication, or device;

2. The procedure, medication, or device is not generally considered to be within the accepted practice standards for the naturopathic profession; and

3. The procedure, medication, or device is not part of the curriculum at an approved school of naturopathic medicine or approved postdoctoral training.

R4-18-802. Informed Consent and Duty to Follow Protocols

A. A physician, medical student engaged in an approved clinical training program, preceptee, or intern who conducts research involving an experimental procedure, medication, or device, shall ensure that all research subjects give informed consent to participate, which states:

1. Whether a physician, preceptee, or an intern is treating the patient;

2. That the patient or legal guardian of the patient understands:

a. The type of treatment the patient is to receive;

b. Each procedure that will be provided to the patient;

c. The risks and benefits of each procedure, medication, or device to be provided;

d. That the patient can withdraw at any time; and

e. That the patient is voluntarily participating; and

3. The physician, medical student engaged in the approved clinical training program, preceptee, or intern has established a protocol as required by subsection (B) that meets the requirements of the institutional review board that approved the protocol.

B. A physician, medical student engaged in an approved clinical training program, preceptee, or intern, who conducts research on humans involving an experimental procedure, medication, or device shall have a protocol for that research approved by an institutional review board.

ARTICLE 9. CERTIFICATE TO DISPENSE

R4-18-901. Definitions

The following definitions apply in this Article:

1. "Applicant" means:
   a. An individual applying for a license and a certificate to dispense; or
   b. A licensee requesting a certificate to dispense only.
2. "Ausculation" means the act of listening to sounds within the human body either directly or through the use of a stethoscope or other means.
3. "Certificate to dispense" means an approval granted by the Board to dispense a natural substance, drug, or device.
4. "Dispense" means the same as in A.R.S. § 32-1581(H).
5. "Drug" means the same as in A.R.S. § 32-1501(15).
6. "Hour" means 50 to 60 minutes of participation.
7. "Medical record" means the same as in A.R.S. § 12-2291.
8. "Nutrient" means the same as in A.R.S. § 32-1501(15)(a)(iii).
9. "Physical examination" means an evaluation of the health of an individual's body using inspection, palpation, percussion, and auscultation to determine cause of illness or disease.

R4-18-902. Qualifications for a Certificate to Dispense

A. To qualify for a certificate to dispense, an applicant shall have completed before the submission date of the application, Board approved training in the safe administration of natural substances, drugs, or devices.

B. The Board approves documentation of the following as evidence of completion of Board approved training in the safe administration of natural substances, drugs, or devices:

1. Graduation from an approved school of naturopathic medicine after January 1, 2005 as referenced in A.R.S. § 32-1525(B)(4); or
2. Completion of a 60 hour or more pharmacological course on natural substances, drugs, or devices that is offered, approved, or recognized by one of the organizations in R4-18-205(B)(1) or R4-18-205(B)(2).

C. If an applicant intends to administer a natural substance or drug intravenously, the Board approved training completed by the applicant shall include administration of a natural substance or drug by intravenous means.

R4-18-903. Application for a Certificate to Dispense; Renewal

A. An applicant for a certificate to dispense shall submit:

1. An application to the Board that contains:
    a. The applicant's:
        i. Full name;
        ii. Naturopathic license number, if known; and
        iii. Social Security number;
    b. If a corporation, a statement of whether the corporation holds tax exempt status;
    c. A statement of whether the applicant holds a drug enforcement number issued by the United States Drug Enforcement Administration, and if so, the drug enforcement number;
    d. A statement of whether the applicant has ever had the authority to prescribe, dispense, or administer a natural substance, drug, or device limited, restricted, modified, denied, surrendered or revoked

by a federal or state agency or court of law, and if so, an explanation that includes:

i. The name and address of the federal or state agency or court having jurisdiction over the matter, and

ii. The disposition of the matter;

e. A statement, signed by the applicant, that the applicant agrees to conform to all federal and state statutes, regulations, and rules; and

f. The date the application is submitted; and

2. Unless exempted by A.R.S. § 32-1530, the fee required by the Board.

B. An applicant for a naturopathic license may request a certificate to dispense as part of a naturopathic license application. When this request is made, approval of the naturopathic license by the Board includes approval of the certificate to dispense.

C. A certificate holder shall renew a certificate to dispense on or before July 1 of each year by submitting:

1. An application to the Board that contains:

a. The applicant's full name;

b. If a corporation, a statement of whether the corporation holds tax exempt status;

c. A statement of whether the applicant has had the authority to prescribe, dispense, or administer a natural substance, drug, device limited, restricted, modified, denied, surrendered or revoked by a federal or state agency or court of law, during the one year period immediately preceding the renewal date and if so, an explanation that includes:

i. The name and address of the federal or state agency or court having jurisdiction over the matter; and

ii. The disposition of the matter; and

d. A statement, signed and dated by the applicant, verifying the information on the application is true and correct and the applicant is the licensee named on the application; and

2. Unless exempted by A.R.S. § 32-1530, the fee required by the Board.

D. The Board shall grant or deny the certificate to dispense or renewal of certificate to dispense according to the time-frames in 4 A.A.C. 18, Article 7, Table 1.

R4-18-904. Dispensing; Intravenous Nutrients

A. To prevent toxicity due to the excessive intake of a natural substance, drug, or device, before dispensing the natural substance, drug, or device to an individual, a certified physician shall:

1. Conduct a physical examination of the individual,
2. Conduct laboratory tests as necessary that determine the potential for toxicity of the individual, and
3. Document the results of the physical examination and laboratory tests in the individual's medical record.

B. For the purposes of A.R.S. § 32-1504(A)(8), a substance is considered a nutrient not suitable for intravenous administration if it is:

1. Not manufactured and supplied for intravenous use by a manufacturer registered with the United States Food and Drug Administration or compounded by a pharmacy licensed in Arizona, another state, or United States territory; or
2. One of the following:
    a. Silver protein, or any substance that contains silver;
    b. Cesium chloride;
    c. Hydrazine sulfate; or
    d. Lipid replacement as used in total parenteral nutrition.